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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,104	11/09/2000	DEXIANG CHEN	APF38.20	4244

7590 03/21/2002
THOMAS P MCCRACKEN
POWDERJECT TECHNOLOGIES INC
6511 DUMBARTON CIRCLE
FREMONT, CA 94555

EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/710,104

Applicant(s)

CHEN ET AL.

Examiner

Stacy S Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 and 30-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election of Group II, claims 24-29, without traverse is acknowledged. Claims 1-23 and 30-35 are pending and withdrawn from consideration, being drawn to non-elected inventions. Claims 24-29 are examined on the merits.

Drawings

2. The drawings are objected to by the Draftsperson, see form PTO 948.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-29 are rejected under 35 U.S.C. 103(a) as being obvious over Sarphie *et al.* (WO 99/27961) in view of McCluskie *et al.* (*Journal of Immunology* (1998) 161:4463-4466). The claims are drawn to a particulate vaccine composition for delivery into or across skin of a vertebrate subject, said composition comprising an antigen or nucleic acid encoding said antigen (viral, bacterial, live, attenuated), an ADP-ribosylating toxin (cholera toxin) as an adjuvant, and an oligonucleotide containing a CpG motif.

Sarphie *et al.* disclose particulate vaccine compositions for transdermal delivery. The vaccine composition comprises antigens (viral, bacteria, live, attenuated), and a CpG

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oligonucleotide, see claims 25-41. Sarphie *et al.* differs from the claimed invention because the reference does not teach the use of cholera toxin (CT) in their particulate vaccine composition.

However, the McCluskie reference discloses subunit vaccines administered intranasally in mice to induce an immune response against Hepatitis B surface antigen. It is taught that CpG motifs and CT act synergistically, resulting in stronger immune responses than either adjuvant administered alone, see abstract.

It would have been *prima facie* obvious to one of ordinary skill in the art to include administration of CT along with CpG in Sarphie's particulate vaccine because McCluskie teaches that CT and CpG motifs act synergistically to achieve a potent mucosal response. One would have been motivated to incorporate CT to improve the adjuvant effect of the particulate vaccine. One would have had a reasonable expectation of success that the CT/CpG adjuvant combination would result in a mucosal immune response because Sarphie and McCluskie teach individually that CT and CpG elicit a mucosal response, and further, McCluskie teaches that together, CT and CpG have a synergistic effect. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

4. **Claims 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenn *et al.* (WO 98/20734) in view of McCluskie *et al.* (*Journal of Immunology* (1998) 161:4463-4466).** The claims are drawn to a particulate vaccine composition for delivery into or across skin of a vertebrate subject, said composition comprising an antigen or nucleic acid encoding said antigen (viral, bacterial, live, attenuated), an ADP-ribosylating toxin (cholera toxin) as an adjuvant, and an oligonucleotide containing a CpG motif.

Glenn *et al.* discloses particulate vaccine compositions for transcutaneous immunization that does not perforate the skin. The vaccine composition comprises antigens and nucleic acid encoding antigens (viral, bacteria, fungus, parasite, live, attenuated), and an ADP-ribosylating exotoxin, CT, see claim 25-33. Glenn *et al.* differs from the claimed invention because the reference does not teach the use of CpG motif adjuvant in their particulate vaccine composition.

However, the McCluskie reference discloses subunit vaccines administered intranasally in mice to induce an immune response against Hepatitis B surface antigen. It is taught that CpG motifs and CT act synergistically, resulting in stronger immune responses than either adjuvant administered alone, see abstract.

It would have been *prima facie* obvious to one of ordinary skill in the art to include administration of CpG along with CT in Glenn's particulate vaccine because McCluskie teaches that CT and CpG act synergistically to achieve a potent mucosal response. One would have been motivated to incorporate CpG to improve the adjuvant effect of the particulate vaccine. One would have had a reasonable expectation of success that the CT/CpG adjuvant combination would result in a mucosal immune response because Glenn and McCluskie teach individually that CT and CpG elicit a mucosal response, and further, McCluskie teaches that together, CT and CpG have a synergistic effect. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion


5. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy S. Brown

Stacy S. Brown
March 19, 2002


HANKYEL T. PARK, PH.D
PRIMARY EXAMINER